K043593

510(k) Summary
Spine-Fix® Biomimetic Bone Cement
December 16, 2005

Submitter	Teknimed S.A. 11 rue Apollo Z.I. Montredon 31240 L'Union France
Contact person	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199
Trade Name	Spine-Fix® Biomimetic Bone Cement
Common name	Polymethylmethacrylate (PMMA) bone cement
Classification name	Filler, Bone Cement (for vertebroplasty) Class II per 21 CFR section 888.3027
Product Code	NDN
Equivalent Device	KYPHX HV-R Bone Cement, MODEL C01A (Kyphon, Inc. - K041584) Spineplex® (Stryker Corp. – K0032945)

Device Description
Spine-Fix is a self hardening and ready to use bone cement with a high amount of radiopaque agent for percutaneous vertebroplasty. It allows an excellent consolidation of the vertebral body and an effective and rapid pain relief.

This type of cement is made of two sterile components: the polymer in powder and the liquid monomer. These two components are in a double sterile packaging. Each unit contains a sterile ampoule of liquid within a blister pack and a powder within a double peelable pouch, the whole being packaged in a box. The liquid component is mainly composed of methyl methacrylate. The major powder component is polymethylmethacrylate (PMMA). Benzoyl peroxide which initiates the polymerisation is included in the polymer powder

Intended Use
Spine Fix cement is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painfull vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Summary Nonclinical Tests
Test data indicate that the final properties of Spine-Fix bone cement are stable and in compliance with the standard reference for bone cement: ISO 5833 "implants for surgery – acrylic resin cements" and are similar to predicate devices.

Summary Clinical Tests
A study of 113 patients at 24 months post-op was conducted. Effectiveness was assessed whether there was improvement in neck pain and disability and whether or not the patient's ability to function in daily life was improved. Safety information was measured by the reporting of adverse events.

One hundred percent of the patients were classified as successful after this surgery. All patients reported mild or no pain at the last follow-up visit and all were classified as normal function or mildly dysfunctional. No patients reported any serious complications as a result of the surgery and all patients were alive at the last follow-up.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Teknimed S.A.
c/o The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K043593
Trade/Device Name: Spine-Fix® Biomimetic Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: December 16, 2005
Received: December 19, 2005

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043593

Device Name: Spine-Fix® Biomimetic Bone Cement

Indications for Use:

Spine Fix cement is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043593